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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,803	04/21/2006	Mary J. Champion	D-3150	5915

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,803	CHAMPION, MARY J.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33,35,36,38,41,44,45,55,57-59,61-65 and 67-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,35,36,38,41,44,45,55,57-59,61-65 and 67-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's request for reconsideration filed 02/04/2008.

Upon further review and reconsideration, a new office action on the merit has been issues as follows:

Claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 67-70 are pending and included in the prosecution.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 67-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hot flashes by placing cooling device at the site of origin of the hot flashes, does not reasonably provide enablement for treating women prone to hot flashes (claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65), or preventing hot flashes (claims 67-70). The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is method for treating hot flashes or preventing hot flashes in women prone to hot flashes. The entire specification disclosed treatment of hot flashes. Nowhere in the specification applicant disclosed prevention of hot flashes. Further, the specification does not enable the treating of the hot flashes in women prone or susceptible to hot flashes, i.e. prevention. The term “treating women prone to” is interpreted by the examiner as "prevention", because symptoms can not treated before they actually happened.

The breadth of the claims: The claims are very broad. The claim encompasses treating women prone to hot flashes or prevention of hot flashes in susceptible patients, and the burden of enabling prevention of hot flashes would be greater than that of enabling a treatment due to the need of additional testing and screening to those

humans prone to or susceptible to hot flashes. The prevention of hot flashes before their occurrence may or may not be addressed by the administration of the instant cooling device because not all menopausal women experience hot flashes, which are one of various symptoms of menopausal syndrome.

The state of the prior art: The state of the art recognized treatment of hot flashes using the gel patches BeKool, and does not recognize the administration of BeKool patches to prevent hot flashes from happening by applying such patches to women prone to hot flashes as required in the instant claims. The state of the art recognizes the treatment of hot flashes as a symptom of menopausal syndrome, but not its cure.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The guidance given by the specification on how to prevent hot flashes is absent. Guidance for treatment of hot flashes as a symptom of menopausal syndrome by applying cooling device to the site of onset of the hot flashes is provided, however, no evidence is provided that hot flashes actually have been prevented from women prone to hot flashes. Furthermore, the specification provides no guidance, in the way written description, on prevention of hot flashes, only treatment of hot flashes as a symptom at the site of its onset, and it is not obvious from the disclosure of treatment of a symptom when it arises if its prevention by applying the same cooling device even before its occurrence will work, simply because it may not occur. In the specification, page 17, lines 14-17, applicant disclosed that:

> "While not wishing to be bound by any particular theory or mechanism of action, it has been discovered that placing the cooling device 12 **in an origin site of a hot flash, for example, in a region of the upper back** between the shoulder blades, can substantially reduce at least one

> symptom of hot flashes associated with menopause, and even substantially alleviate hot flashes associated with menopause. In certain situations, it has been found that placement of a cooling device 12 **at a region in proximity to the cervical and thoracic vertebrae substantially at the onset of a hot flash** or even in anticipation of a hot flash can effectively prevent the hot flash from spreading throughout a woman's body."

Therefore, the disclosure is directed to placing cooling device at the site o onset of the hot flashes, i.e. hot flashes must happens first before treatment by applying the cooling device. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the methods of using fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of significant guidance from the specification or prior art with regard to complete prevention of hot flashes from prone women using the instant cooling devices applied to specific areas makes practicing the claimed invention unpredictable in terms of the prevention of the occurrence of the hot flashes even before been experienced by women because it is not known who is going to have them.

The presence or absence of working examples: The specification discloses treatment of hot flashes using cooling device. No working examples to show preventing hot flashes in prone women. Therefore, the specification has enabled only treating hot flashes as a symptom of menopausal syndrome by applying cooling device at the site of origin of the hot flashes and further disclosed applying the cooling device at the onset of experiencing the hot flashes, and not treatment of prone women or prevention of hot flashes before their occurrence, because they may not occur in all menopausal women.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant method for preventing hot flashes without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Response to Arguments

3. Applicant's arguments filed 02/04/2008 have been fully considered but they are not persuasive. Applicant argues that the claims do not recite "prevention" and are directed to "treating". Dependent claims 67-70 recite the patch is effective to prevent a hot flash associated with menopause from spreading throughout the body of the woman. Such spreading of a hot flash throughout the body of the woman represents an increase in the severity of the hot flash, and does not prevent the hot flash from happening.

In response to this argument, it is arguing that the expression "women prone to hot flashes" as instantly claimed by generic claims 33, 55 and 61 is interpreted by the examiner as "prevention". Additionally, in the specification, in page 17, lines 14-17, applicant disclosed that:

> "While not wishing to be bound by any particular theory or mechanism of action, it has been discovered that **placing the cooling device 12 in an origin site of a hot flash**, for example, in a region of the upper back between the shoulder blades, **can substantially reduce at least one symptom of hot flashes associated with menopause**, and even substantially alleviate hot flashes associated with menopause. In certain situations, it has been found that **placement of a cooling device 12 at a region in proximity to the cervical and thoracic vertebrae** substantially **at the onset of a hot flash** or even in anticipation of a hot flash can effectively prevent the hot flash from spreading throughout a woman's body."

Therefore, applicant disclosed that the cooling device is placed on the origin site of the hot flashes, and did not show by any means that if the device is placed on the back of a woman will prevent hot flashes from spreading. Contrarily, applicant disclosed that the device is placed at the origin of the hot flashes at upper back, and in proximity to the cervical and thoracic vertebrae, to prevent spreading of the flashes. Therefore, hot flashes have to happen first before applying the cooling device.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 33, 41, 44, 45, 61, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over the product “BeKool” by Kobayashi Healthcare, INC., and was presented as: “Product Concept Test” by itself or in view of the article by “Pharmacy Key”, September 2003.

BeKool is cooling gel sheet used for treating hot flashes. The presentation implies that the gel sheets been in use before the article date August 14, 2003. The present method of treating requires only the step of applying the patch. The site of application of the patch in the upper back or between the clavicles does not impart patentability to the claimed method because the patch will work the same way

effectively and equally regardless of the site of its application. The instruction and packaging do not impart patentability of the claims. The claims are obvious by the reference since it has been held by the court that when the only difference between the prior art product and the claim is the "written instruction to the consumer", the claim is obvious over the art. See *In re Ngai 03-1524*. The product of the prior art is expected to be packaged since all medicaments are supplied in packages to ensure their safety against contamination and stability during storage. BeKool does not contain any active agent in the gel sheet.

Additionally, applicant disclosed in page 4, lines 15-20 that: "Although the exemplary embodiment of the invention is directed to placing the cooling device on the back of a woman, the cooling device may be placed on any site of a woman's body, preferably on or at any hot flash origin site, or a site where the hot flash, for example, the first symptom of the hot flash, is felt first".

The article "Pharmacy Key" teaches that the transdermal patch containing lidocaine can be applied on intact skin on the back.

Therefore, it would have been obvious to one having ordinary skill in the art a the time of the invention to treat hot flashes using a cooling gel as disclosed BeKool product concept test, and apply the cooling gel to the site of origin of the hot flashes, or applying the cooling gel at the back of the women, as disclosed by the article "Pharmacy Key" that patches can be applied to the back of patients, motivation would arise from the logic that applying the patch on the back wherein it can be hidden under cloth in inconspicuous location to provide self confidence to the wearer since it has been held

by the court that aesthetic changes that have no mechanical function cannot be relied upon to patentability distinguish the claimed invention from the prior art. See *In re Seid*, 161 F.2d 229, 73 USPQ 431 (CCPA 1947).

6. Claims 35, 36, 38, 55, 57-59, 62-65, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over "BeKool" product in view of any of JP 2002119529 ('529) or US 6,224,899 ('899).

The BeKool product concept test is discussed under previously as set forth in this office action.

However, BeKool does not describe the gel as water containing gel comprising polyacrylic component and gas permeable substrate as claimed by claims 35, 36, 38, 55, 57-59, 62-65, 67 and 68.

JP '529 teaches cooling patch which can maintain the cooling effect while being able to cool the affected part at an early stage and can maintain a cooldown delay, said patch comprises water permeable film covered with hydrous paste of polyacrylic acid (abstract; paragraphs 0004-0008).

US '899 teaches adhesive cooling gel contains large amount of water spread on moisture permeable sheet (abstract; col.8, lines 61-66). The adhesive cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue (col.1, lines 53-55, 59-61). The cooling patch can be applied locally to the area of discomfort without limitation

to the body part such as fever, inflammation, pain or sprain to assuage the discomfort (col.8, lines 41-58).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a cooling sheet to treat hot flashes as disclosed BeKool, and made the sheet of hydrous material comprising polyacrylic acid on a water permeable sheet as disclosed by JP '529 or US '899, motivated by the teaching of JP '529 that such a cooling patch structure and materials can maintain the cooling effect while being able to cool the affected part at an early stage and can maintain a cooldown delay, or motivated by the teaching of US '899 that such an adhesive cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue, with reasonable expectation of having cooling patch or sheet comprising water permeable backing and polyacrylic acid paste or gel that is able to maintain the cooling effect and preserve the coolness of the site of its application to treat hot flashes successfully and effectively.

Response to Arguments

7. Applicant's arguments with respect to claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65 have been considered but are moot in view of the new ground(s) of rejection.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,956,963 disclosed treatment of hot flashes using wrist cooler.

BeKool picture shows product is packaged, and instruction is provided. The pamphlet of the product “Immediate, convenient and discrete relief from hot flashes … anywhere anytime”, stated that "If and when a hot flash occurs, simply peel off the strip covering the adhesive backing, apply the cooling soft gel sheet to the rear of the neck under your clothing".

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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